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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,442	06/25/2003	George Baran	6298/431	2937

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CHICAGO, IL 60610

EXAMINER

CHAPMAN, GINGER T

ART UNIT	PAPER NUMBER
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3761

MAIL DATE	DELIVERY MODE
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06/28/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/606,442

Applicant(s)

BARAN, GEORGE

Examiner

Ginger T. Chapman

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 64-81 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 64-81 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the claims

Claims 64-81 are pending in the application.

Claim Objections

Applicant is advised that should claim 77 be found allowable, claim 81 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 73 is objected to because of the following informalities: line 2 recites "said strip". While the claims provide antecedent basis for the "stripe" recited in lines 2 and 3, antecedent basis is not provided for "said strip". Therefore the examiner is considering this a typographical error of "stripe". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 79 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a wire, does not reasonably provide enablement for attaching first and

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second ends of a tether to the distal and shaft sections. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. In particular, careful review of the Specification at [0127-0128] and Figure 16 indicates the disclosure in the Specification enables a wire to be attached, but does not reasonable provide enablement for the claimed “tether”. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 77-78, 64-74, 76 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chester (WO 82/00413 A1) in view of Smith et al. (US 5,031,613) as evidenced by Blake et al. (US 3,634,924).

With regard to claims 77, 66-68, 76, and 81, Chester discloses a method of forming a medical tube (page 1, lines 2-5) comprising: providing a multi-lumen extruded compliant plastic tubing (page 3, lines 30-33, page 8, lines 16-21); inherently discloses heating the tubing to a glass transition temperature and exposing the plastic tubing to high energy radiation to crosslink polymers since it is made by extrusion (see Wikipedia article for description of extrusion process); forming a flexible j-shaped distal section (page 8, lines 16-21).

Chester does not expressly disclose forming a plurality of orifices at the distal section. Smith discloses a multi-lumen plastic catheter 2 with a j-shaped distal section (column 2, lines 10-15, lines 50-53, figure 1) and forming a plurality of perforations/orifices 10 at the distal

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section (column 2, lines 25-33) to provide medicinal aerosol particles which are inhaled into the lungs (column 1, lines 50-53, column 2, lines 12-15, column 3, lines 26-30, figure 3). One would be motivated to modify the tube of Chester to have a plurality of orifices at a distal section for distribution of liquid medication since the references are in the same field of endeavor; multi-lumen j-shaped medical catheters. Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to modify the catheter, thus providing a plurality of orifices.

With regard to the limitation of the tube being multilumen, Chester discloses the tube is formed by coextrusion, coextrusion is widely known in the catheter art as fully capable of forming multilumen catheter body tubing. This is evidenced by Blake, made of record in a previous office action, as clearly disclosing that multilumen tubing is known in the art as being economically produced by extrusion. Therefore the limitation of the tubing being multilumen does not provide additional patentable weight.

With regard to claim 78, Smith further discloses the j-shaped distal section maintains its orientation with the plurality of orifices 10 pointed toward a proximal end of the catheter (figures 2-4).

Regarding claims 69-74, Chester further discloses providing graduated radiopaque markings along the catheter in the form of stripes 16, 18 that are made via a coextrusion process (page 3, lines 33-36, page 6, line 34-page 7, line 7).

Claims 64-65, 75 and 79-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chester (WO 82/00413 A1)/Smith et al. (US 5,031,613) as applied to claim 77 above, and further in view of Blake et al. (US 3,634,924).

With regard to claims 64-65, Blake explicitly discloses cutting the tubing at a distal end to the desired length (c. 2, l. 3). Further, the references detailed *supra* disclose a cut medical catheter as discussed above with respect to claim 77.

Chester/Smith disclose the method as discussed above with respect to claim 77. Chester/Smith do not expressly disclose a wire at a distal end or in the wall of the catheter. Blake discloses multilumen catheter tube 10 formed by extrusion (column 1, line 73-column 2, line 9) of a compliant thermoplastic material (column 2, line 75-column 3, line 2) and useful for injection of therapeutic agents (column 2, lines 66-68). Blake further discloses round wire 30 inserted in lumen 11 so the lumen holds its shape (column 2, lines 39-57; figure 4). One would be motivated to modify the catheter lumen of Chester/Smith with the tether wire of Blake to maintain the catheter shape since the references both disclose extruded multi-lumen catheters. Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to modify the catheter, thus providing a wire.

Response to Arguments

Applicant's arguments filed 3 April 2007 have been fully considered but they are not persuasive.

I. Applicant submits Chester does not expressly disclose multilumen tubing. This argument is not persuasive as detailed *supra* under claim 77.

II. Applicant submits Smith depicts an hourglass shaped section of the catheter rather than a j-shaped lumen. This argument is not persuasive for the following reasons:

1. As best depicted in Figure 1, the section of the catheter body that is the substantially identical structure of the instant claimed "j-shaped distal section" exhibits a J-shape.

2. As depicted in all prior art references made of record, forming a particular shape catheter section is known in the art and therefore obvious. Further as seen in all figures depicting various geometries, the figures illustrate that the tubing shape is purely a matter of choice, when there is a variety of possible shapes it means that the designer can choose any shape he wants.

3. Finally, after review of the prior art and Applicants' specification, it is noted that Applicant provides no criticality for the specific j-shape. The specification contains no disclosure of either the critical nature of the claim limitations nor any unexpected results arising therefrom, and that as such the limitations were arbitrary and therefore obvious. Such unsupported limitations cannot be the basis for patentability, since where patentability is said to be based upon particular dimensions or another variable in the claim, the applicant must show that the chosen variables are critical. *In re Woodruff*, 919 F.2d 1575, 1578, 16 USPQ 2d 1934 (Fed. Cir. 1990). One having ordinary skill in the art would be able to determine the ideal shape for a particular catheter based on the intended use of the catheter as a matter of obvious design choice.

For these reasons, the examiner respectfully traverses Applicant's arguments and maintains the art rejections of the rejected claims.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginger T. Chapman whose telephone number is (571) 272-4934. The examiner can normally be reached on Monday through Friday 9:30 a.m. to 6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ginger Chapman
Examiner, Art Unit 3761
6/24/07



TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

